DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-303/S-032

Novartis Pharmaceuticals Corporation
Attention: Ms. Donna Vivelo
One Health Plaza
East Hanover, NJ 07936-1080

SUPPLEMENT APPROVAL

Dear Ms. Vivelo:

Please refer to your supplemental new drug application (NDA) dated September 18, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lopressor HCT (metoprolol tartrate and hydrochlorothiazide) 50/25, 100/25 and 100/50 mg Tablets.

This supplemental new drug application provides for revisions to the package insert:

Addition of the following statement to the **PRECAUTIONS/Drug Interactions** section of the labeling

> "Both digitalis glycosides and beta-blockers slow atrioventricular conduction and decrease heart rate. Concomitant use can increase the risk of bradycardia."

Deletion of the following statement from the **WARNINGS/Hypertension and Angina/Cardiac Failure** section of the labeling

> "Both digitalis and Lopressor slow AV conduction."

We have completed our review of this application, and it is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon electronic labeling text. We will transmit the SPL version of the labeling submitted on September 18, 2007 to the National Library of Medicine for public dissemination.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

Marketing the product with labeling that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Dan Brum, Pharm.D., Regulatory Project Manager, at (301)796-0578.

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc: Enclosed Labeling Text

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Norman Stockbridge

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